

Remarks

Status of the Claims

Upon entry of the above amendments, claims 26-30 will remain pending in the present application, claims 31-34, 61 and 62 having been cancelled in the above amendments. Claims 26, 27 and 28 are the independent claims.

Summary of the Bases for Objection /Rejection

Claims 26 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154.

Claims 31-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis).

Claims 31-34 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis).

Claims 31-34 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis).

Claims 26-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates).

Each of these five (5) bases for rejection is addressed in Sections I-V, respectively, which follow.

I. Provisional Rejection Based On Obviousness Type Double Patenting

Claims 26 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154. The Applicants will address this issue at such time as claims are allowed either in the present application or in the '154 application.

II. 35 U.S.C. § 102(b) over U.S. Pat. 5,147,367 (Ellis)

Claims 31-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). Applicants maintain that claims 31-34 are

patentable over Ellis. However, claims 31-34 have been cancelled to advance prosecution of the remaining claims. The cancellation of claim 31-34 renders this rejection moot. Therefore this rejection will not be addressed further.

III. 35 U.S.C. § 103(a) over U.S. Pat. 5,147,367 (Ellis)

Claims 31-34 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,147,367 (Ellis). Applicants maintain that claims 31-34 are patentable over Ellis. However, claims 31-34 have been cancelled to advance prosecution of the remaining claims. The cancellation of claim 31-34 renders this rejection moot. Therefore this rejection will not be addressed further.

IV. 35 U.S.C. § 103(a) over U.S. Pat. 5,716,358 (Ochoa) in view of Ellis

Claims 31-34 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 5,716,358 (Ochoa) in view of U.S. Pat. 5,147,367 (Ellis). Applicants maintain that claims 31-34 are patentable over Ochoa in view of Ellis. However, claims 31-34 have been cancelled to advance prosecution of the remaining claims. The cancellation of claim 31-34 renders this rejection moot. Therefore this rejection will not be addressed further.

V. 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates)

Claims 26-34 and 61-62 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates). Applicants maintain that claims 31-34 and 61-62 are patentable over Siebels in view of Coates. However, claims 31-34 and 61-62 have been cancelled to advance prosecution of the remaining claims. Therefore the rejection with respect to these claims will not be addressed further. With regard to claims 26-30, the Applicants respectfully disagree with the Patent Office's rejection as discussed below.

The Office Action relies on Siebels for its disclosure of "an assembled bone implant made by assembling separate bone implant pieces together by aligning bores of adjacent pieces;" and introducing "pins into the aligned bones to hold the implant pieces

together.” [Office Action at page 5.] However, the only materials actually described in the Siebels reference from which the disks and/or anchoring pins described therein can be made are “fiber reinforced plastic,” see Siebels translation at p. 3, such as “carbon-fiber reinforced plastic.” See Siebels translation at p. 6. The Siebels reference does not describe any other materials from which its implants or anchoring pins can be made.

The Office Action acknowledges that Siebels does not disclose the use of cortical bone for making implant pieces. To make up for this deficiency, the Office Action cites to Coates, alleging that Coates “teaches that it was well known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61.” [Office Action at page 6.] The Office Action then concludes that it would have been obvious to make the discs and pins of Siebels implant out of cortical bone for the same reasons the [sic] Coates teaches doing the same. The Applicants respectfully disagree.

Applicants submit that a person of skill in the art would not combine the teachings of the Siebels and Coates references in the manner required by the Office Action. Such a person would not substitute the fiber reinforced plastic used by Siebels with cortical bone pursuant to Coates. Siebels employs fiber reinforced plastic as the material for its discs. Siebels notes that “Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, **in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.**” See Siebels translation at p. 4 (emphasis added). In contrast, the Coates reference states that there would be concerns about stability when bone is used. For example at column 3, lines 17-32, Coates states “Both allograft and autograft present additional difficulties. Graft alone **may not provide the stability required** to withstand spinal loads.” [Emphasis added.] Coates acknowledges the difficulties in creating implants from allograft or autograft bone. Coates goes on to discuss the difficulty of creating such an implant.

Several attempts have been made to develop a bone graft substitute which avoids the disadvantages of metal implants and bone grafts while capturing advantages of both. In each case, developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been **extremely difficult or impossible.**

[Coates, col. 3, lines 38-39] [emphasis added.] A person of skill in the art would not substitute the fiber reinforced plastic, which is said by Siebels to have rigidity and strength, with cortical bone, which, according to Coates, may not provide the required stability.

Additionally, in discussing the Coates reference, the Office Action also states that “[a]ssembly of the implant pieces was not an issue.” Applicants submit that this is indicative of the nonobviousness. Coates does not even suggest a bone graft assembled from a plurality of allograft bone portions layered to form a graft unit.

For at least these reasons, the combination of the Siebels and Coates references would not have rendered claims 26-30 obvious to a person skilled in the art at the time that the Applicants’ invention was made.

Conclusion

Although the Office Action makes various statements regarding claims 26-34, 61, 62 and the cited references that are now moot in light of the above, applicants expressly reserve the right to challenge such statements in the future should the need arise (for example, if such statement(s) become relevant by appearing in a rejection of any current or future claim).

Claims 26-30 are currently pending. Claims 26-30 currently stand rejected. In view of the amendments and arguments provided herein, Applicants believe that all bases for rejecting claims 26-30 have been overcome. Applicants respectfully submit that claims 26-30 of the instant application are in a condition for allowance. The Examiner is invited to telephone the applicants’ undersigned attorney at (312) 775-8213, if any unresolved matters remain.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Account No. 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Respectfully submitted,

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